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September 15, 2000

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Jane E. Henney, M.D.

Commissioner, Food and Drug Administration

5600 Fishers Lane

Room 1471 - Parklawn Bldg. - MS HF-1

Rockville, Maryland 20857

RE: Prescription Drug User Fee Act [Docket No. 00N-1364]

Dear Dr. Henney:

The Cure for Lymphoma Foundation (CFL) appreciates the opportunity to share its views on the success of the Prescription Drug User Fee Act (PDUFA). CFL regrets that it will not be able to participate in the September 15, 2000, public meeting, but we are encouraged that the agency is soliciting input from a broad cross section of organizations, including patient organizations, before it develops its priorities for PDUFA reauthorization.

For individuals with lymphoma, timely access to state-of-the-art therapies is absolutely critical. Therefore, we strongly support PDUFA because it has contributed to the reduction in the decision and approval times for drugs and biologicals.

We would like to address the specific questions posed by the FDA in the notice of the public meeting:

1. We believe the reduction in the decision and approval times for drugs and biologicals is the primary benefit offered to patients by PDUFA. The maintenance of these management improvements and the achievement of additional enhancements in the review process should remain the primary focus of this legislation.

CFL is concerned that the availability of user fee revenues not undermine the Congressional commitment to appropriate federal funds for the agency on an annual basis. We recommend that user fee revenues be available only if appropriated funds reach a certain threshold level. It is critical that the taxpayers support the regulatory mission of the agency, and this commitment is best demonstrated by federal funding.

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2. Accountability for the use of appropriated or other funds should be a feature of all federal programs, and we recommend that PDUFA performance goals be retained. Although industry, agency officials, and Congress are best equipped to define proper performance goals, we encourage the agency to seek advice from patient organizations on performance goals and implementation of PDUFA generally.
3. CFL does not have an opinion as to the precise percentage of drug review program costs that should be funded by user fees, but we are sensitive to the importance of the public's confidence in FDA. Therefore, we recommend that the current user fee system not be modified in any way that might create the appearance that the regulated industry has undue influence because the agency is so heavily dependent upon fees from the industry. CFL cautions against use of user fee revenues to support agency programs and responsibilities outside the product review function. We believe it is important that the agency be able to account for user fee revenues by describing the impact on review activities; this accountability would not be possible if user fees were used to support other core agency activities.

CFL appreciates this opportunity to share its views on this important issue.

Sincerely,



Ilene Penn Miller  
Executive Director

cc: Dockets Management Branch (HFA-305)  
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